PTO/SB/21 (02-04) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE e Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. **Application Number** 10/785,215 TRANSMITTAL Filing Date February 23, 2004 **FORM** First Named Inventor Craig P. Roberts et al. Art Unit (to be used for all correspondence after initial filing) 1614 Examiner Name Unknown Attorney Docket Number 51283-00002 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance communication Drawing(s) to Technology Center (TC) Fee Transmittal Form Appeal Communication to Board Licensing-related Papers of Appeals and Interferences Fee Attached Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) Amendment/Reply Petition to Convert to a **Proprietary Information** After Final **Provisional Application** Power of Attorney, Revocation Status Letter Change of Correspondence Address Affidavits/declaration(s) Other Enclosure(s) (please Terminal Disclaimer Extension of Time Request Identify below): Subsitute Form PTO-1449 (3 pgs) and Request for Refund **Express Abandonment Request** Non-US Patent References listed on substitute for PTO-1449 (35) CD, Number of CD(s) Information Disclosure Statement Remarks Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Michelle S. Glasky Preston Gates & Éllis, LLP Individual name Reg. No.: 54,124 Signature Date CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. Typed or printed name Dulcie Donoso Fontt Date Signature

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



## CERTIFICATE OF MAILING

I hereby certify that on March 1, 2005, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage to in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dulcie Donoso Fontt

## **PATENT**

Inventor: Roberts, Craig P. et al.

Serial No.: 10/785,215

Filing Date: February 23, 2004

Title: PLASMA DETOXIFICATION

SYSTEM AND METHODS OF

USE

Examiner: Unknown

Group Art Unit: 1614

Atty Docket No.: 51283-00002

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

## INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Alexandria. VA 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. §§ 1.56. 1.97 and 1.98, and in accordance with the provisions in the Manual of Patent Examining Procedure §§609 and 707.05(b), enclosed is a copy of the substitute for FORM PTO-1449 listing the references that are known to applicant. Applicants enclose copies of each of the listed references which are not U.S. patents.

This art is being filed for consideration in compliance with § 1.97 within the following time period:

37 C.F.R. § 1.97 (b) This information disclosure statement is being filed by the applicant for consideration and entry before the mailing of a first office action on the merits.

The submission of the above-described documents does not constitute an admission nor should it be construed as a representation that a search has been made,

PATENT Docket No. 51283-00002

Applicant: Roberts et. al. Serial No.: 10/785,215 Group Art Unit: 1614

construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

Applicant reserves the right to antedate or otherwise remove the documents as references.

It is respectfully requested that the listed references be considered in the examination of this application and identified on the list of references cited on the patent issuing for this application. Applicant also requests that an initialed copy of the substitute for FORM PTO-1449 be entered in the application file and returned to applicant with the next communication from the Office in accordance with MPEP § 609.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Applicant belives that no fee is due with this communication; however, if the Commissioner deems a fee is due, the Director is hereby authorized to charge any fees to Deposit Account No. 50-1329. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
PRESTON GATES & ELLIS LLP

Dated: 3/1/05

Registration No. 54,124

PRESTON GATES & ELLIS LLP 1900 Main Sreet, Suite 600 Irvine, California 92614-7319 Telephone: (949) 253-0900 Facsimile: (949) 253-0902

Customer Number: 45,200

PTO/SB/08A (08-03)

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Under the Paperwork Substitute for form 1449A GRAULING Complete if Known 10/785,215 Application Number Filing Date 02/23/2004 INFORMATION DISCLOSURE Craig P. Roberts STATEMENT BY APPLICANT First Named Inventor 1614 Group Art Unit **Examiner Name** Unassigned (use as many sheets as necessary) 51283-00002 3 **Attorney Docket Number** of Sheet

		The state of the s	U.S. PATENT DOCUME		Pages, Columns, Lines, Where
Examiner	Cite	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited	Relevant Passages or Relevan
Initials	No.1	Number-Kind Code <sup>2 (if known)</sup>		Document	Figures Appear
	AA	US -4,127,481	11/28/1978	Malchesky et al.	
	AB	US -4,231,871	11/04/1980	Lipps et al.	
	AC	US -4,267,047	05/12/1981	Henne et al.	
	AD	US -4,269,708	05/26/1981	Bonomini et al.	
	AE	US -4,617,115	10/14/1986	Vantard	
	AF	US -4,747,822	05/31/1988	Peabody	
	AG	US -4,769,037	09/06/1988	Midcalf	
	AH	US -5,015,388	05/14/1991	Pusineri et al.	
	Al	US -5,571,418	11/05/1996	Lee et al.	
	AJ	US -6,008,049	12/28/1999	Naughton et al.	
	AK	US -6,186,146	02/13/2001	Glickman	
	AL	US -6,287,516	09/11/2001	Matson et al.	
	AM	US -6,372,482	04/16/2002	Mitrani	
	AN	US -2001/0051106	12/13/2001	Matson et al.	

				FOREIG	IN PATENT DOCUMEN	NTS		
Examiner Initials	Cite No.1	Office <sup>3</sup>	Foreign Patent Docur  Number <sup>4</sup>	Kind Code <sup>5</sup>	Date of Publications of Cited Documents MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ'
	AP	WO	00/02603		01/20/2000	Bioscience Research Associates		
	AQ	WO	03/009885		06/02/2003	Immunocept LLC		

Examiner	Date	
Signature	 Considered	

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.4. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the senial number of the patent documents. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Papelicant is to place a check mark here if English language Translation is attached.

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ork Reduction Act of	1990, no persons are	e required to res	John to a collection of information unless	s it contains a valid Olvid Control Humber.	
1449A/PTO			Complete if Known		
			Application Number	10/785,215	
<b>FORMATION</b>	DISCLOSUR	E	Filing Date	02/23/2004	
TATEMENT E	Y APPLICAN	T	First Named Inventor	Craig P. Roberts	
			Group Art Unit	1614	
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		NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.1							
	AR	Anand A.C., Nightingale P., Neuberger J.M., Early indicators of prognosis in fulminant hepatic failure: an assessment of the King's criteria, J Hepatology, 1997; 26:62-68.						
	AS	Ash S.R., Treatment of Acute Hepatic Failure with Encephalopathy: A review, Int. J. Artif Organs, 1991; 14:191-195.						
	AT	Awad S.S. et al., A novel stable reproducible model of hepatic failure canines, J. Surg. Res., 2000; 94:167-71.						
	AU	Bende S. et al., Elimination of endotoxin from the blood by extracorporeal activated charcoal hemoperfusion in experimental canine endotoxin shock, Circulatory Shock, 1986; 19:239-244.						
	AV	Ellis A.J. et al., Temporary extracorporeal liver support for several acute alcoholic hepatitis using the BioLogic-DT,. Int. J. Artif. Organs, 1999; 22:27-34.						
	AW	Falhenhagen D. et al., Franctionated plasma separation and adsorption system: A novel system for blood purification to remove albumin bound substances, Artif. Organs, 1999; 23:81-6.						
	AX	Hughes R.D. and Williams R., Use of sorbent columns and haemofiltration in fulminant hepatic failure, Blood Purif., 1993; 11:163-9.						
į	Hughes R.D. et al., Artificial liver support in acute liver failure: a review of studies at King's, Artif. Organs 1992; 16:167-70.							
	Hughes R.D., In-vitro blood compatibility studies on a new polymer-coated charcoal for haemoperfusion, The Inter'l Journal of Artificial Organs, 1980; 3(5): 277-279.							
	BA	Hughes R.D., Platelet function during haemoperfusion in acute liver failure, The Inter'l Journal of Artificial Organs, 1980; 3(1):30-34.						
	BB	Kellum J.A. and Dishart M. K., Effect of Hemofiltration Filter Adsorption on Circulating IL-6 Levels in Spectic Rats, Critical Care 2002, 6:429-433.						
	BC	Makin A.J. et al., System and hepatic hemodynamic changes in acute liver injury. Am. J. Physiol., 1997; 272:G617-G625.						
	BD	Morimoto T. et al., Plasma absorption using bilirubin-absorbent materials as a treatment for patients with hepatic failure, Artificial Organs 1989, 447-452.						
	BE	lullen KD, Dasarathy S., Hepatic encephalopathy. ER Schiff et al. (eds), Schiff's Diseases of the ver, 8 <sup>th</sup> edition, Lippincott-Raven Publishers, Philadelphia, 1999						
	Nagaki M. et al., In vitro plasma perfusion through adsorbents and plasma ultrafiltration to remove endotoxin and cytokines, Circulatory Shock 1992; 38:182-8.							
BG Nagaki M. et al., Removal of endotoxin and cytokines by absorbent and the effect of plass binding, Liver Unit, King's College School of Medicine and Dentistry 1991;. 4:43-50.								
	ВН	Nakae H, Yonekawa C, Wada H, Asanuma Y, Sato T, Tanaka H. Effectiveness of combining plasma exchange and continuous hemodiafiltration (combined modality therapy in a parallel circuit) in the treatment of patients with acute hepatic failure, Ther Apher., 2001;5:471-475.						
Examiner Signature		Date Considered						

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Substitute for form	1449A/PTO			Complete if Known		
				Application Number	10/785,215	
IN	<b>IFORMATION</b>	DISCLOSUR	RE	Filing Date	02/23/2004	
STATEMENT BY APPLICANT				First Named Inventor	Craig P. Roberts	
				Group Art Unit	1614	
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Sheet	3	of	3	Attorney Docket Number	51283-00002	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	BI	Odnopozov V.A. et al. Effect of hemocarboperfusion on organ blood flow and survival in procine endotoxic shock. Crit. Care Med., 1996; 24:2020-2026.	
	BJ	Peltekian KM, Levy GA: Role of cytokines and immune mechanisms in acute liver failure. In Acute Liver Failure. Edited by Lee WM et al. (eds.), Cambridge Press; 1997.	
	ВК	Rahman T.M. and Hodgson H.J Review article: Liver Support Systems in Acute Hepatic Failure. Aliment. Phamacol. Ther., 1999; 13: 1255-1272.	
	BL	Ronco C, Brendolan A, Lonnemann G, Bellomo R, Piccinni P, Digito A, Dan M, Irone M, La Greca G, Inguaggiato P, Maggiore U, De Nitti C, Wratten ML, Ricci Z, Tetta C., A pilot study of coupled plasma filtration with adsorption in septic shock, Crit Care Med 2002;30:1250-55.	
	ВМ	Ryan C.J. et al., Preclinical evaluation of haemosorbents, The Inter'l Journal of Artificial Organs 1986; 9-5:293-296.	
	BN	Ryan C.J. et al., Repeated membrane plasma separation with on-line sorbent treatment of plasma in the conscious rat, 1986; Artificial Organs, 10(2):135-144.	
	ВО	Schiødt FV, Atillasoy E, Shakil AO, et al., Etiology and outcome for 295 patients with acute liver failure in the United States. Liver Transpl Surg., 1999; 5:29-34.	
	BP	Schiødt FV, Rochling FA, Casey DL, Lee WM, Acetaminophen toxicity in an urban county hospital. N Engl J Med., 1997; 337:1112-1117.	
	BQ	Strange J. et al., Liver support by extracorporeal blook purification-A clinical observation, German Ministry for Research and Technology, Germany, 2000; 6(5):603-613.	
	BR	Sudan DL, Shaw BW Jr. Fox IJ, Langnas AN, Long-term follow up of auxiliary orthotopic liver transplantation for the treatment of fulminant hepatic failure. Surgery, 1997; 122(4):777-778.	
	BS	Sussman N.L., Chong M.G., Koussayer T. et al. Reversal of fulminant hepatic failure using an extracorporeal liver assist device. Hepatology, 1992; 16: 60-65.	
	ВТ	Terblanche J. and Hickman R., Animal models of fulminant liver failure, Digest. Dis. Sci. 1991; 36:770-4.	
	BU	Tetta C. et al., Endotoxin and cytokine removal in sepsis, Ther. Apher 2002, I 6:109-115	
	BV	Wedon J.A., Harrison P.M., Keays R., Williams R., Cerebral blood flow and metabolism in fulminant liver failure, Hepatology, 1994; 19: 1407-141319.	
,	BW	Wehler M. et al., Short-term prognosis in critically ill patients with cirrhosis assessed by prognostic scoring systems, Hepatology, 2001; 34:255-261.	
	ВХ	Williams R., New directions in acute liver failure, J Royal College of Physicians of London, 1994; 28:552-559.	

Examiner	Date	
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